REMARKS

This is in response to the Office Action mailed on November 28, 2008 for the above-referenced application. Applicant has amended Claims 21, 37-42, and 45-46. Claim 1 has been amended and new dependent Claim 48 has been added to be also directed to inhibiting wound healing responses, support for which can be found in paragraph [0077] of the application as published. Thus, Claims 21, 23-27, and 37-48 remain pending for examination. Applicant respectfully requests reconsideration of the pending claims in view of the remarks and amendments contained herein.

Discussion of Claim Rejections under 35 U.S.C. § 112

The Office Action stated that the term "signal generator" (which is recited in line 4 of Claim 21) has insufficient antecedent basis. Accordingly, Applicant has amended Claim 21 to positively recite "a medical device connected to a signal generator."

The Office Action stated that the term "critical structure or feature of an implanted portion" in Claim 37 has insufficient antecedent basis. Accordingly, Applicant has amended Claim 37 to positively recite "a critical structure or feature of an implanted portion of the device."

The Office Action stated that the term "one or more first electrodes" and "one or more second electrodes" in Claims 38-41 are unclear if they are the same as the terms in Claim 37. The Office Action suggested inserting the term "said" before these terms. Applicant has amended Claims 38-41 accordingly.

The Office Action stated that it is unclear how a device can be percutaneous as recited in Claim 42. The Office Action suggested reciting "placed percutaneous" (or "positioned percutaneously") instead. Applicant has amended Claim 42 accordingly.

The Office Action stated that the term "the further" in Claim 45 lacks antecedent basis. Applicant has amended Claim 45 to add the term "first medical device portion" such that the claim recites "wherein the first medical device portion further comprises" and such that the claim has proper antecedent basis.

The Office Action stated that Claim 45 is incomplete because there is no connection between the term "therapeutic agent delivery element" and any other claim elements. Likewise, the Office Action also stated that Claim 46 is incomplete because there is no connection between the terms "biofluids sampling element" and any other claim elements. Applicant has amended Claims 45 and 46 to tie the respective structures to the critical structure or feature of Claim 37. In view of the foregoing, Applicant respectfully requests removal of these rejections under § 112.

Discussion of Claim Rejections under 35 U.S.C. § 102(e)

The Office Action has rejected Claims 21, 23-27, 37-43, and 45-47 under § 102(e) as being anticipated by Kroll et al (U.S. Patent No. 7,203,550). Applicant respectfully submits that Kroll does not anticipate each and every claim limitation of Claim 21.

Functional limitation of independent Claim 21 limits structure

Claim 21 recites: "***wherein*** said variation ***is configured to*** guide the migration of selected cell types to produce a longer useful lifetime of the device by limiting undesirable cellular responses to foreign bodies and/or wounds." (emphasis added) In the Office Action, the Examiner does not appear to give patentable weight to the functional limitation recited after the "wherein" and "configured to" clauses. In particular, the Examiner states that "[i]t is further noted the desired results of migrating cell types to produce a longer useful lifetime are not germane to the patentability of these device claims." Applicant respectfully disagrees.

The determination of whether the claim language following a clause, such as "wherein," "whereby," or "adapted to," (which is similar to Applicant's claimed "configured to") is a claim limitation, depends on the specific facts of the case. M.P.E.P. § 2111.04. A "wherein" clause can place limits (i.e., patentable weight) on the element that it introduces, as discussed in *Griffin:* "the Board did not err in giving limiting effect to the 'wherein' clauses because they relate back to and clarify what is required." *Griffin v. M. Bertina*, 285, F. 3d 1029, 1033 (Fed. Cir. 2002).

Applicant's functional limitation that limits the device structure is defined by both a "wherein" and a "configured to" clause. These terms define the structure of the claimed device such that Applicant's structure can be distinguished from the prior art. As such, this functional

limitation limits structure and should be given patentable weight. The M.P.E.P. states that "[a] functional limitation is an attempt to define something by what it does, rather than by what it is ... [a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." M.P.E.P. § 2173.05(g). As in the *Griffin* case cited above, the "wherein" clause in Claim 21 refers back to and clarifies the claimed variable surface charge of the device. As such, Applicant's "wherein" clause introduces a limiting feature that should receive patentable weight because it limits structure. Thus, devices according to Claim 21 are configured to "guide the migration of selected cell types," "produce a longer useful lifetime of the device" and accomplishes this by "limiting undesirable cellular responses to foreign bodies." Thus, these features cannot be ignored.

Kroll does not inherently disclose this functional limitation

Kroll discloses an apparatus for treating an infection which may occur in a biofilm which surrounds an implanted cardiac stimulation device (e.g., pacemaker). See Kroll, Col. 1, lns. 35-47. Figure 4 of Kroll illustrates an implanted cardiac stimulation device 120, shown below for the Examiner's convenience:

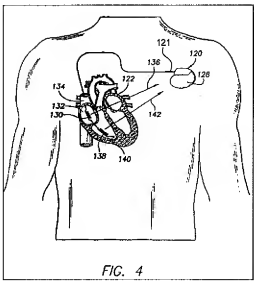

FIG. 4

As illustrated, the implanted cardiac stimulation device 120 provides current to the patient's heart 122 using two electrodes 130, 138. Kroll's apparatus provides an electrical

treatment that enables an antibiotic to successfully treat the infection without having to remove the implanted cardiac stimulation device. See Kroll, Col. 1, lns. 35-47.

In contrast, independent Claim 21 recites "said surface charge being variable in response to a time dependent signal from the signal generator, and wherein said variation is configured to ***guide the migration of selected cell types to produce a longer useful lifetime of the device by limiting undesirable cellular responses to foreign bodies*** (emphasis added)." Kroll does not disclose the features of Claim 21 for at least the following reasons.

First, Kroll does not disclose a variation configured to "***guide*** the migration of selected cell types to produce a longer useful lifetime of the device (emphasis added)." The Office Action recites the features of Kroll, and then states that Kroll achieves the same device limitations and further is capable of achieving the same inherent results and benefits as the claimed device, (without reciting specific claim limitations). In the Office Action's response to arguments, the Examiner stated that this feature was not germane to patentability. However, it is a proper limitation and it is not inherent in Kroll.

It has been established that "the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P. § 2112, Sec. IV, 8th Ed., Rev. 5 (citing *In re Rijckaert*, 9 F.3d 1531, 1534, emphasis in original). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.' " *Id.* (quoting *In re Robertson*, 169 F.3d 743, 745, emphasis added). Indeed, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Id.* (quoting *Ex parte Levy*, 17 USPQ2d 1461, 1464, emphasis in original).

Kroll teaches a system by which an electrical current is used to destroy bacteria residing in a biofilm of an implanted cardiac treatment device. Kroll, Col 9, lines 45-48. Kroll describes using an average current density of 150 microamperes per square centimeter to be therapeutic. *Id.*, col. 9, lines 48-52. Kroll notes that an electric current applied at that density could interfere with the heart's conduction, thereby pacing the heart or inducing an arrhythmia. *Id.*, col. 9, lines

52-55. Thus, Kroll teaches varying the current in order to avoid an arrhythmia. For example, Kroll suggests the duration of the electrical current varies according to the heart's refractory period or in a frequency range which is too rapid to affect the heart. *Id.*, col. 9, lines 22-27.

In contrast, the device of Claim 21 is directed to varying the surface charge in a manner that controls the migration of certain cell types. Directing the cell migration minimizes fibrous capsule formation and enhances the useful lifetime of the medical device. For example, the electric fields are preferably configured to guide fibroblasts away from the device. As stated in the specification, "fibroblasts in particular have been shown to migrate towards the cathode under the influence of an applied current." Specification, paragraph [0042]. The cathode has the negative bias. Specification, paragraph [0043].

This is different from Kroll. First, as set forth above, Kroll designs the variation to minimize cardiac interference, which is totally unrelated to guiding cell migration. Furthermore, Kroll Figure 4 shows electric currents 136 and 142 flowing towards the implanted device 120. As a result, fibroblasts would likely migrate towards the implanted device, not away from it. Thus, the Kroll system is actually configured to produce the opposite effect of the present claims. It may also be noted that one of ordinary skill in the art, when reading the Kroll reference, would find indications that anti-bacterial activity is the only effect producible by the electric fields. This is demonstrated by the claim language of Kroll which specifies an "infection control current." No suggestion that the current can or should be configured for "limiting undesirable cellular responses to foreign bodies and/or wounds" can be found in Kroll at all. Therefore, Kroll does not anticipate Claim 21.

Claims 23-27 and 37-47 depend either directly or through another claim from independent Claim 21, and incorporate all the limitations recited therein. Applicant respectfully submits that for at least the above reasons, and their own features, these claims are patentable. Therefore, upon allowance of Claim 21, for at least the reasons discussed herein, Applicant respectfully submits that Claims 23-27 and 37-47 are allowable. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 5/28/09

By: 

Thomas R. Arno
Registration No. 40,490
Attorney of Record
Customer No. 20,995
(619) 235-8550

7027842_1
042209